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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/718,818	11/21/2003	Matthias Stiene	LFS-5021	1342

27777 7590 03/03/2006

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EXAMINER	
DRYDEN, MATTHEW DUTTON	
ART UNIT	**PAPER NUMBER**
3736	

DATE MAILED: 03/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/718,818	STIENE ET AL.	
	Examiner	Art Unit	
	Matthew D. Dryden	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *21 November 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/15/05, 11/21/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7, 12, 15 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Erickson et al (6080116).

Regarding claim 1, Erickson et al discloses an interstitial fluid collection and constituent measurement device comprising:

a penetration member having a channel (penetration member can be seen around element 46' in Figure 7),

a fluid flow regulator disposed within the channel of the penetration member, adapted to reduce bodily flow rate through the penetration member, as discussed in the specification of the applicant the fluid flow regulator is just a narrow bore cylinder, (see around elements 12' and 14' in Figure 7).

Regarding claim 2, the regulator is capable of minimizing bodily fluid flow rate variation, through the penetration member.

Regarding claim 3, the regulator is capable of optimizing a dead volume of the device, wherein the dead space could be the area within the needle where the tube is located.

Regarding claim 4, see column 6, lines 40-58.

Regarding claim 5, the narrow bore cylinder is snugly fit against the needle in Figure 7, the cylinder has an internal diameter of about 114 microns-140 microns, and the exterior diameter of the needle is .36 millimeters -.23 millimeters (see Column 12, lines 64-67), so the inner diameter would be within the range of 100-500 microns.

Regarding claim 6, the fluid flow regulator as discussed in the rejection of claim 1 is a narrow bore cylinder.

Regarding claim 7, see Column 5, lines 46-51.

Regarding claim 12, see Column 6, lines 40-48.

Regarding claim 15, Erickson et al provides a device comprising:

a penetration member having a channel (penetration member can be seen around element 46' in Figure 7),

a fluid flow regulator disposed within the channel of the penetration member, adapted to reduce bodily flow rate through the penetration member, as discussed in the specification of the applicant the fluid flow regulator is just a narrow bore cylinder, (see around elements 12' and 14' in Figure 7),

and method steps of penetrating a target site and extracting bodily fluid from the target site (see column 7, lines 9-53).

Regarding claim 16, see Column 7, lines 34-38.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 8 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Erickson et al in view of Moreno (5354537). Erickson et al discloses the claimed invention except for the narrow bore-channel having a gradually decreasing diameter. Moreno shows a portion of a skin penetration member that includes a bore that decreases in diameter towards the distal end of the piercing member, so that surface tension of the sample fluid at the free end will balance a vertical column of sample fluid in the elongated body without dripping (see Column 4, lines 57-61). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Erickson et al to include a bore channel that gradually deceases in diameter as taught by Moreno, so that surface tension of the sample fluid at the free end will balance a vertical column of sample fluid in the elongated body without dripping.

Regarding claim 13, Erickson et al discloses the claimed invention except for the skin penetration member being made out of stainless steel. However, Erickson does disclose that the preferred gauge of the needle is limited by the mechanical integrity of commercially available needles, which includes stainless steel needles. Regarding the tube being made out of a polymer see Column 6 lines 18-28. Moreno teaches a skin penetration member being made of stainless steel (see Column 4, line 42), which is commonly used in the art so that the needle does not react with other metals and is less likely to breakdown and rust. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Erickson et al to include a skin penetration member that is made out of stainless steel, as taught by Moreno, so that the needle does not react with other metals and is less likely to breakdown and rust.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Erickson et al in view of Duchamp (5893834). Erickson et al discloses the claimed invention except for the device comprising a narrow bore channel that has a diameter that decreases in a step like manner. Duchamp discloses a blood collection device that and the end of the device around element 4) is fitted into a needle or cannula (see Column 3, lines 62-65), and the step like sections of the channel are to allow for the control of blood flow into the volume of the channel and can be adjusted by sticking a device in the upper barrel of the channel (see Figure 1A, and columns 3-6, lines 41- 25). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Erickson et al to include a decreasing stepped diameter as

taught by Duchamp, to allow for the control of blood flow into the volume of the channel and can be adjusted by sticking a device in the upper barrel of the channel.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Erickson et al.

Erickson et al discloses an interstitial fluid collection device comprising:

a penetration member having a channel (penetration member can be seen around element 46' in Figure 7),

a fluid flow regulator disposed within the channel of the penetration member, adapted to reduce bodily flow rate through the penetration member, as discussed in the specification of the applicant the fluid flow regulator is just a narrow bore cylinder, (see around elements 12' and 14' in Figure 7)

the narrow bore cylinder is snugly fit against the needle in Figure 7, the cylinder has an internal diameter of about 114 microns-140 microns, and the exterior diameter of the needle is .36 millimeters -.23 millimeters (see Column 12, lines 64-67), so the inner diameter would be within the range of 100-500 microns, which is capable of being approximately 300 micrometers.

Erickson et al does not disclose expressly the narrow-bore channel having a width of 12 micrometers and a height of 15 micrometers.

At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to provide a narrow-bore channel having a width of 12 micrometers and a height of 15 micrometers because Applicant has not disclosed that such dimensions for the width and the height provides an

advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the channel (capillary tube) taught by Erickson et al because both dimensions perform the same function of collecting interstitial fluid and reducing the flow of the fluid through the channel.

Therefore, it would have been an obvious matter of design choice to modify Erickson et al to obtain the invention as specified in claim 10, because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of Erickson et al.

Claims 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Erickson et al in view of Kensey (6200277). Erickson et al discloses the claimed invention except for the device comprising a fluid flow regulator with a coating of anti-thrombogenic coating. Kensey teaches it is known to provide a capillary tube, which is considered to be the flow regulator in the rejection of claim 1 above, with an anti-thrombogenic coating to prevent blood from adhering to the tube's internal walls (see Column 10, lines 23-38). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Erickson et al to have a fluid flow regulator with anti-thrombogenic coatings, as taught by Kensey, to prevent blood from adhering to the tube's internal walls.

Prior Art

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. Pat. No. 5,294,325 Liu discloses a miniaturized fluid conveying device and methods of use thereof

U.S. Pat. No. 6,306,103 Tyler discloses a blood/body fluid collection apparatus and method

U.S. Pat. No. 6,755,802 Bell discloses a whole blood sampling device

U.S. Pat. No. 5,104,705 Quackenbush discloses an extruded polymer tubes for blood and fluid sampling

U.S. Pat. No. 5,048,530 Hurwitz discloses a method of using an amniocentesis needle with improved sonographic visibility.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew D. Dryden whose telephone number is (571) 272-6266. The examiner can normally be reached on Monday-Friday 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MDD